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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>C12Q 1/68</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 00/29618</b> <b>(43) International Publication Date:</b> 25 May 2000 (25.05.00)
<b>(21) International Application Number:</b> PCT/US99/26471 <b>(22) International Filing Date:</b> 10 November 1999 (10.11.99) <b>(30) Priority Data:</b> 60/108,089 12 November 1998 (12.11.98) US <b>(71) Applicant (for all designated States except US):</b> UNIVERSITY OF VIRGINIA PATENT FOUNDATION [US/US]; Suite 1-110, 1224 West Main Street, Charlottesville, VA 22903 (US). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> POWELL, Steven [US/US]; 2175 Anderson Lane, Charlottesville, VA 22911 (US). GRAMLEY, William [US/US]; 3207 Snowberry Court, Wilmington, NC 28409 (US). <b>(74) Agent:</b> BREEN, John, P.; University of Virginia Patent Foundation, Suite 1-110, 1224 West Main Street, Charlottesville, VA 22903 (US).		<b>(81) Designated States:</b> AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

**(54) Title:** NON-INVASIVE DETECTION OF HELICOBACTER PYLORI INFECTION**(57) Abstract**

The present invention relates to a kit and method of purifying DNA from stool samples of vertebrate species. The DNA is recovered in sufficient purity to allow the DNA to be amplified by PCR, thus allowing the identification of pathogenic organisms present in the digestive tract.

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/26471

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :C12Q 1/68

US CL :435/6

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

STN databases: biosis, medline, caplus, lifesci, embase  
WEST Derwent, USPAT, EUROPAT, JAPPAT databases.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,403,924 A(COVER et al) 04 April 1995, see Abstract, Col.12, lines 52-69, and Col. 14 lines 10-25.	1-17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

09 FEBRUARY 2000

Date of mailing of the international search report

17 MAR 2000

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

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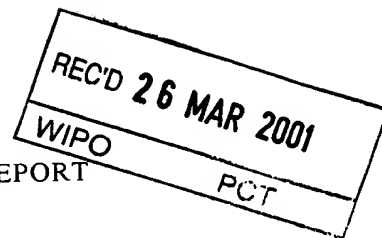
JANELLE TAYLOR

Telephone No. (703) 305-0273

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

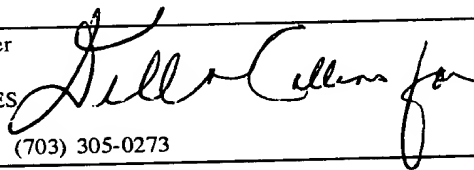
(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 00362-02	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/26471	International filing date (day/month/year) 10 NOVEMBER 1999	Priority date (day/month/year) 12 NOVEMBER 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/68 and US Cl.: 435/6		
Applicant UNIVERSITY OF VIRGINIA PATENT FOUNDATION		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 3 sheets.  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
 These annexes consist of a total of 0 sheets.

- This report contains indications relating to the following items:
  - ☒ Basis of the report
  - ☐ Priority
  - ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
  - ☐ Lack of unity of invention
  - ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain documents cited
  - ☐ Certain defects in the international application
  - ☐ Certain observations on the international application

Date of submission of the demand  08 JUNE 2000	Date of completion of this report  27 FEBRUARY 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  GARY JONES 
Facsimile No. (703) 305-3230	Telephone No. (703) 305-0273

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/26471

## I. Basis of the report

1. With regard to the **elements** of the international application:\*

☒ the international application as originally filed

☒ the description:

pages 1-18, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

☒ the claims:

pages 19-22, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

☒ the drawings:

pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

☒ the sequence listing part of the description:

pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE  
☒ the claims, Nos. NONE  
☒ the drawings, sheets/figs NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/26471

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. statement

Novelty (N)

Claims	<u>1-17</u>	YES
Claims	<u>NONE</u>	NO

Inventive Step (IS)

Claims	<u>NONE</u>	YES
Claims	<u>1-17</u>	NO

Industrial Applicability (IA)

Claims	<u>1-17</u>	YES
Claims	<u>NONE</u>	NO

## 2. citations and explanations (Rule 70.7)

Claims 1-17 lack an inventive step under PCT Article 33(3) as being obvious over Cover et al. The claims are drawn to a method for isolating amplifiable nucleic acids from a solid stool sample, comprising solubilizing the sample, mixing it with a chaotropic agent such as a detergent, heating it, separating the precipitate from the lysed cell solution, extracting the protease solution, and recovering the nucleic acids.

Cover et al teaches obtaining DNA from a stool sample and digested by restriction endonuclease and comparing the results of different strains.

Cover et al. do not teach using a detergent to separate the DNA from the stool sample. It was well known in the art, however, at the time of the invention to wash stool samples prior to the isolation of nucleic acids. This was well known because it would have been considered an essential step in the isolation of nucleic acids.

----- NEW CITATIONS -----  
NONE